

## REMARKS

After entry of this Amendment, the pending claims are: claims 54-77. The Office Action dated May 4, 2006 has been carefully considered. Claims 1, 3-18, 20-24 and 26 have been canceled without prejudice. Applicants desire to start prosecution anew as such all prior Amendments and Remarks are respectfully withdrawn. Claims 2, 19, 25 and 27-53 were previously canceled. Claims 54-77 have been added. No new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following Remarks is respectfully requested.

In the Office Action dated May 4, 2006, the Examiner rejected claims 1, 3-24 and 26 under 35 U.S.C. 103(a) as being unpatentable over the published article *Contact of Hydroxyapatite Spacers with Split Spinous Processes in Double-Door Laminoplasty for Cervical Myelopathy* by Shigery Hirabayashi and Kiyoshi Kumano ("Hirabayashi") in view of U.S. Patent No. 6,511,509 to Ford *et al.* ("Ford").

### CLAIM 1, 3-24 AND 26

Claims 1, 3-24 and 26 were rejected as being unpatentable over Hirabayashi in view of Ford. Claims 1, 3-24 and 26 have been canceled without prejudice as the Applications desire to start prosecution anew. As such, all prior Amendments and Remarks are explicitly withdrawn. With the cancellation of claims 1, 3-24 and 26, the Examiner's rejection is deemed moot. Withdrawal of this rejection is respectfully requested.

### NEWLY ADDED INDEPENDENT CLAIM 54

Newly added independent claim 54 requires, *inter alia*, a thin-walled tubular allograft body, the thin wall tubular body including a first end, a second end, an outer surface, a bore extending from the

first end to the second end, the bore defining an inner surface, and a thin wall extending between the outer surface and the inner surface.

In an effort to expedite prosecution of newly added independent claim 54, the Applicants hereby offer the following Remarks regarding Hirabayashi and Ford.

As an initial matter, it is respectfully submitted that the Examiner has not identified any reason why a person of ordinary skill in the art would have combined Hirabayashi, which is directed to a laminoplasty implant for insertion between adjacent cut bone ends of a spinous process, with Ford, which is directed to an intervertebral implant for insertion between adjacent vertebrae, other than it would teach all of the elements of the previously pending claims. (*See KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007) “[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently known, in the prior art ... important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.”)

It is respectfully submitted that the Applicants through their own effort and expense derived the device as currently claimed in newly added independent claim 54. It is respectfully submitted that without the benefit of the Applicants' disclosure, it would not be obvious for one of ordinary skill in the art to redesign the Hirabayashi's implant to include a bore extending from the first end to the second end as disclosed by Ford, especially since Hirabayashi was concerned with overcoming inadequate contact between the prior art laminoplasty implants and the cut ends of a patient's spinous process. Incorporating a bore as disclosed in Ford is expressly contrary to the stated purpose of Hirabayashi,

namely to increase contact between the laminoplasty implant and the cut ends of the patient's spinous process. If anything, Hirabayashi explicitly taught away from the invention of independent claim 54 by stressing the need to increase the amount of contact in-between the implant ends and the cut ends of a patient's spinous process. (See *Tec Air, Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353 (Fed. Cir. 1999) "[t]here is no suggestion to combine ... if a reference teaches away from its combination with another source ... 'A reference may be said to teach away when a person of ordinary skill, upon reading of the reference ... would be lead in a direction divergent from the path that was taken by the applicant.'")

Moreover, it is respectfully submitted that without the benefit of the Applicants' disclosure, it would not be obvious for one of ordinary skill in the art to redesign the Hirabayashi's STSS implant to be manufactured from an allograft material as disclosed in Ford. Hirabayashi discloses a new laminoplasty implant (the STSS implant) made from hydroxyapatite, an artificial polymer. This is an important distinction and not one which should be discarded easily as the requirements for designing, manufacturing and machining an implant out of allograft material are very different from the requirements for designing, manufacturing and machining an implant out of an artificial material. In addition, Hirabayashi explicitly distinguished its newly developed STSS implant from implants made of allograft stating that allograft implants resulted in excessive pain and discomfort to the patient and increased surgery time. See Hirabayashi, page 1, "[i]n the original procedure, small bone blocks from the iliac crest were grafted to keep the split spinous processes separated ... However, pain and discomfort ... were not uncommon ... In 1990, Harata and Ito developed an artificial spacer, made of hydroxyapatite instead of graft bone. See also page 3, "[w]ith the use of a spinous process spacer in

laminoplasty instead of autograft bone from the iliac crest, surgery time is shortened and blood loss is decreased ...” If anything, Hirabayashi explicitly taught away from the invention of independent claim 54 by stressing the advantages of manufacturing a laminoplasty implant from an artificial material and by designing an implant from an artificial material, the implant having a specific optimized shape according to Hirabayashi.

In addition, it is respectfully submitted that without the benefit of the Applicants’ disclosure, it would not be obvious for one of ordinary skill in the art to redesign the Hirabayashi’s STSS implant to include a tubular shape as disclosed in Ford. Hirabayashi discloses a trapezoidal implant, wherein the implant is both trapezoidal in the axial and frontal sections. In fact, Hirabayashi, which was explicitly concerned with developing a new and improved shape for a laminoplasty implant explicitly distinguished the shape of the STSS implant from prior art implants that incorporated non trapezoidal shapes in both the axial and frontal sections. See Hirabayashi, page 265, “[t]he characteristic shape of the STSS spacer is trapezoidal on both the axial and frontal sections. In contrast, the shapes of other spacers are rectangular on the frontal section and trapezoidal on the axial section only. This is a fundamental difference in shape between the STSS spacer and other spacers.” If anything, Hirabayashi explicitly taught away from the invention of independent claim 54 by stating that a fundamental difference of the STSS implant was that it included a trapezoidal shape on both the axial and frontal sections.

Moreover, even if one was to properly combine Hirabayashi with Ford, which Applicants believe it is not, the combination would still not teach all of the limitations of newly added independent claim

54. Independent claim 54 requires, *inter alia*, a thin-walled tubular allograft body. It is respectfully submitted that neither Hirabayashi or Ford, either alone or in combination, teach, disclose, or suggest a thin-walled tubular body.

As admitted by the Examiner, Hirabayashi does not disclose a bore extending from the first end to the second end. Rather, the Examiner relies upon Ford to disclose a central bore. It is respectfully submitted that Ford does not overcome the shortcomings of Hirabayashi since Ford also fails to disclose, teach or suggest a thin walled tubular body. Rather, Ford discloses an allograft spacer sized and configured for insertion in-between adjacent vertebrae. This is an important distinction as the requirements for an intervertebral implant are different from the requirements of an implant sized and configured for a laminoplasty procedure. The Ford spacer includes top and bottom bone engaging surfaces for contacting the endplates of adjacent vertebrae. The spacer further includes a central hollow bore extending from the top bone engaging surface to the bottom bone engaging surface. It is respectfully submitted that Ford does not disclose a thin-walled tubular body. Rather, it is respectfully submitted that the wall in Ford is relatively thick and must be so in order to support the anticipated loads.

Therefore, it is respectfully submitted that neither Hirabayashi or Ford, either alone or in combination, disclose, teach or suggest all of the limitations of newly added independent claim 54 since neither reference discloses a thin-walled tubular body.

Moreover, it is respectfully submitted that contrary to the Examiner's assertion, it would not be obvious for one of ordinary skill in the art to combine Hirabayashi with Ford since modifying the

Hirabayashi' STSS implant to be made from an allograft material and to include a tubular body having a bore would be contrary to the explicit teachings of Hirabayashi.

For at least the above-identified reasons, it is respectfully submitted that neither Hirabayashi or Ford, either alone or in combination, disclose, teach or suggest all of the limitations of independent claim 54. Thus, it is respectfully submitted that independent claim 54 is allowable over the cited prior art. Allowance of independent claim 54 is respectfully requested.

Furthermore, as claims 55-77 all depend from independent claim 54, it is submitted that these claims are equally allowable. Allowance of claims 55-77 is also respectfully requested.

## CONCLUSION

A fee of \$790.00 is believed due for this submission. The Commissioner is hereby authorized to charge this and any other fee which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

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Respectfully submitted,

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